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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,470	11/29/2000	Daniella I. Zheleva	CCI-014	1635
959 7590 04/05/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER KOSAR, ANDREW D	
			ART UNIT 1654	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/726,470	ZHELEVA ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25, 36, 41, 42, 44-47 and 55-84 is/are pending in the application.
- 4a) Of the above claim(s) 17-19, 21-24, 36, 41, 42, 44-47, 55-65 and 67-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 20, 25 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicants' papers filed 16 November 2006. Pending claims are 16-25, 36, 41, 42, 44-47 and 55-84, with claims 17-19, 21-24, 36, 41, 42, 44-47, 55-65, and 67-84 remaining withdrawn from consideration as now generic or species specific claims are allowable for reasons herein stated and for those reasons of record. Applicants are advised that once a claim is found allowable in its entirety it will be made of record as being allowable. Claims 16, 20, 25 and 66 are under consideration.
2. As stated in the previous office action dated 19 October 2005, the species of SEQ ID NO: 35 is free of the prior art.

Withdrawal of Objections and Rejections

3. The rejections and/or objections made in the prior office action 16 May 2006, which are not explicitly stated below, in original or modified form are withdrawn.
4. Applicants' arguments filed 16 November 2006 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Objections

5. (Withdrawn) Objection to Claim 20 is withdrawn as obviated by Applicants' amendments.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. (Withdrawn) Rejection of Claim 20 under 35 U.S.C. 112, second paragraph, is withdrawn as obviated by Applicants' amendments to the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. (Maintained in Part) Rejection of Claims under 35 U.S.C. 102(b) as being anticipated by WO 96/01329 ('1329), wherein the '1329 reference teaches in Figure 4A the peptide CSF A10 of the sequence DSTRALYF, is maintained. This sequence meets the limitations of the rejected claims. X1, X3, X4 and X5 are each a natural amino acid and X2 is serine. Applicants argue that the sequence is not isolated as is required by the instant claims; however, the sequence is specifically identified in the cited Figure 4A. Applicants have not shown cited support for their argument that the sequence is not isolated. Furthermore, if the '1329 sequence was not isolated or clearly identified for one of skill in the art to see, then Applicants have not established why the '1329 reference would list it as an individual sequence versus listing it as a portion of a larger sequence. Therefore, the rejection is maintained.

10. (Necessitated by Amendment) Claims 20 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Kisfaludy et al., Attempts to synthesize Δ^5 -3-Ketosteroid Isomerase, Pept. Proc. Eur. Pept. Symp., 14th, 1976, pages 239-249. Kisfaludy et al. teach a peptide fitting the instantly claimed generic formula of SEQ ID NO: 2, wherein the two C-terminal amino acid residues are reversed (see page 243 Table 2, peptide 111-117).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 16, 20, 25 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-33 and 71-76 of copending Application No. 10/441,952 ('952). Although the conflicting claims are not identical, they are not patentably distinct from each other because '952 claims a species which anticipates the instant claims as well as claiming generic formulas that read on the instantly claimed generic formulas. For example, '952 teaches SEQ ID NO: 467 of claim 19 wherein the SEQ ID NO: 467 is His-[Ser or Ala]-[Lys or Cys]-Arg-Arg-Lys-Xaa-Phe. The peptide may also be reversed at the last two amino acid residues of the C-terminal, and may be cyclic. A preferred embodiment anticipating the instant claims is SEQ ID NO: 48-49, amongst others. Although considered withdrawn SEQ ID NOs: 169-170 are claimed in '952 at claim 25.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Conclusion

13. The Species of SEQ ID NO: 35 is free of the prior art. No claims are allowable.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


B. DELL CHISM
PRIMARY EXAMINER